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Paper 36

Entered: 6 February 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

KATHERINE L. **MOLNAR-KIMBER**,
CRAIG E. CAUFIELD, and
TIMOTHY D. OCAIN
Junior Party
(Application 09/576,951),

v.

RICHARD **SEDRANI**
and VALERIE QUESNIAUX
Senior Party
(Patent 6,635,745).

Patent Interference No. 105,429
(Technology Center 1600)

Before McKelvey, Senior Administrative Patent Judge, and Lane, and Moore, Administrative Patent Judges.

Lane, Administrative Patent Judge.

Decision - Motions - Bd.R. 125(a)

I. Statement of the case

Sedrani has moved to redefine the interfering subject matter by substituting proposed Count 2 for Count 1. (Paper 22).[1] Molnar-Kimber opposes. (Paper 24). We GRANT the Sedrani motion.

II. Issue

The issue before us is whether Sedrani proposed Count 2 should be substituted for Count 1. The issue turns on whether Count 1 encompasses two separately patentable inventions.

III. Findings of fact

The record supports the following findings of fact by a preponderance of the evidence.

1. Count 1 reads as follows:

> Claim 1 of Sedrani (6,635,745)
>
> or
>
> claim 33 of Molnar-Kimber (09/576,951).

(Paper 1 at 4).

2. Sedrani has been accorded an earlier constructive reduction to practice, i.e., benefit for the purpose of priority, of the following applications:

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[1] Sedrani requested oral argument. (Bd. R. 124(a)) (Paper 31). Molanar-Kimber did not. Under the present circumstances where we are granting Sedan's motion, we believe oral argument is not necessary.

US 09/072,278 filed 4 May 1998

US 08/532,837, filed 5 October 1995

PCT/EP94/01006, filed 30 March 1994

UK 9307491.2, filed 8 April 1993

(Paper 1 at 4).

3. Sedrani claim 1 is:

An immunogenic conjugate which is 1) rapamycin bearing an immunogenic protein at position 40 or 28; or 2) 40-O-(2-hydroxyethyl) rapamycin bearing an immunogenic protein at position 28.

4. Molanar-Kimber claim 33 is:

A monoclonal antibody having binding specificity for a rapamycin, wherein said antibody is obtained using an immunogen comprising a molecule selected from the group consisting of a rapamycin having a linking group at the 42 position, a rapamycin having a linking group at the 31 position, and a rapamycin having a linking group at both the 42 position and the 31 position, wherein said molecule is conjugated to an immunogenic carrier material via said linking group.

5. Proposed count 2 reads as follows:

An immunogenic conjugate which is rapamycin bearing an immunogenic protein at position 40 or 28

or

a monoclonal antibody having binding specificity for a rapamycin, wherein said antibody is obtained using an immunogen comprising a molecule selected from the group consisting of a rapamycin having a linking group at the 42 position, a rapamycin having a linking group at the 31 position, and a rapamycin having a linking group at both the 42 position and the 31 position, wherein said molecule is conjugated to an immunogenic carrier material via said linking group.

(Paper 22 at 2).

6. Proposed count 2 differs from count 1 because proposed count 2 does recite an immunogenic protein that is "40-O-(2-hydroxyethyl) rapamycin bearing an immunogenic protein at position 28".

7. In its motion, Sedrani refers to 40-O-(2-hydroxyethyl)rapamycin as "RAD" and to 40-O-(2-hydroxyethyl)rapamycin bearing an immunogenic protein at position 28 as a "RAD conjugate." (Paper 22 at 1).

8. According to Sedrani, RAD conjugates are separately patentably from the rapamycin conjugates and rapamycin antibodies encompassed by proposed Count 2. (Paper 22 at 2).

9. In support of its position, Sedrani relies on the declaration testimony of Dr. Walter Schuler (Exh. 1026) and Dr. Achim A. Jungbluth (Exh. 1040).

10. Dr. Schuler has "vest industry experience in the development of immunosuppressants, such as [RAD]" (Exh. 1026 at ¶ 2).

11. Based on Dr. Schuler's experience and education as set forth in his curriculum vitae (Exh. 1001) and his declaration (Exh. 1026 at ¶¶ 2-7), we find that Dr. Schuler is qualified to testify on the issues at hand in this interference.

12. Based on Dr. Schuler's testimony, we find that:

a. RAD is a derivative of rapamycin. (Exh. 1026 at ¶ 18).

b. The Molnar-Kimber application describes several derivatives of rapamycin but does not claim or describe the RAD compound or any RAD conjugate. (Exh. 1026 at ¶¶ 41 and 42).

c. Assuming rapamycin conjugates and monoclonal antibodies made therefrom to be in the prior art, there would have been no suggestion to one skilled in the art to make RAD conjugates. (Exh. 1026 at ¶ 45).

d. "[N]one of the pertinent prior art of which Dr. Schuler is aware describes RAD compounds or RAD conjugates." (Exh. 1026 at ¶ 47)

13. Dr. Jungbluth testified that he has "approximately 11 years' experience in the field of tumor immunology" and that he has been involved in research concerning "the generation and characterization of therapeutic and diagnostic monoclonal antibodies; and antigen characterization for vaccine-based or antibody-based immunotherapy of cancer." (Exh. 1040 at ¶¶ 2 and 6).

14. Based on Dr. Jungbluth's experience and education as set forth in his curriculum vitae (Exh. 1031) and his declaration (Exh. 1040 at ¶¶ 2-6), we find that Dr. Jungbluth is qualified to testify on the issues at hand in this interference.

15. Dr. Jungbluth's testimony is consistent with that of Dr. Schuler.

16. Based on Dr. Jungbluth's testimony, we find that:

(a) RAD is not disclosed in the Molnar-Kimber applications (Exh. 1040 at ¶ 14), and

(b) assuming rapamycin conjugates and monoclonal antibodies to be in the prior art, there would have been no suggestion to one skilled in the art to make a RAD conjugate (Exh. 1040 at ¶¶ 29-39).

17. While Molnar-Kimber had an opportunity to cross-examine both Dr. Schuler and Dr. Jungbluth, it elected not to cross-examine either.

18. Molnar-Kimber contends that Sedrani failed to show why proposed Count 2 should be adopted over Count 1 since, according to Molnar-Kimber, RAD conjugates are encompassed by proposed Count 2. (Paper 24 at 1).

19. Molnar-Kimber notes that proposed "Count 2 recites, in part, a monoclonal antibody having binding specificity for '**a** rapamycin'" and that "the term '**a** rapamycin' is generic terminology for "rapamycin and any derivative thereof" including RAD. (Paper 24 at 1, bold in original).

20. Molnar-Kimber has not pointed out with a specific citation to a page and line of its application, and it is not apparent to us, where its application expressly discloses RAD per se.

21. Molnar-Kimber also argues that, in its motion 1, Sedrani erroneously stated that RAD was not known in the art. (Paper 24 at 2).

22. Molnar-Kimber relies on US patent 5,258,389 to Goulet et al. (Exh. 1007), cited in the Sedrani involved patent (Exh. 1002 at 2:8-24) which Molanar-Kimber says discloses a reaction producing 40-O-(hydroxylalkyl)-rapamycin. (Paper 24 at 2).

23. Goulet issued on 2 November 1993 from an application filed on 9 November 1992.

24. Goulet is prior art under 35 USC §102(e) to both the involved Molnar-Kimber application and the involved Sedrani patent.

25. Goulet discloses a generic structural formula I where "R^1 and R^2 are independently selected from" thirteen possible substituents most of which can also contain their own substituents. (Exh. 1007 at col. 3-6).

26. Formula I encompasses hundreds of compounds.

27. However, Molnar-Kimber argues that structural formula I of Goulet discloses RAD when:

(1) option 9(a), i.e., hydroxyl substituted C_1-C_{10} alkyl, is selected for substituent R^1 with ethyl being selected as the C_1-C_{10} alkyl, and,

(2) hydrogen is selected as R^2.

28. Moreover, Molnar-Kimber directs us to reaction scheme F, which is said to show "the synthesis or a 40-O-(hydroxyalkyl)-rapamycin, where the hydroxyl-substituted alky group is C_1-C_8 alkyl. (Paper 24 at 2-3).

29. Reaction scheme F is described as the production of a compound where "R^1 is unsubstituted or substituted alkyl, alkenyl, or alkynyl"[2] and without specification as to the structure of R^2. (Exh. 1007 at col. 21, l. 55-col. 22, l.9).

30. Molnar-Kimber also relies on US patent 5,665,772 to Cottons et al. which is said to disclose RAD. (Exh. 2018).

31. Cottons issued on 9 September 1997 and has a 35 USC §102(e) date of 7 April 1995.

32. Cottons is not prior art to either the involved Molnar-Kimber application or the involved Sedrani patent.

33. Molnar-Kimber reasons that, because Count 2 encompasses rapamycin derivatives and conjugates thereof and RAD was a known rapamycin derivative, RAD conjugate is at least prima facie obvious in view of Count 2.

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[2] The illustrated reaction shows a product having a hydroxyl substituted "A" group. We understand A to be alkyl, alkenyl, or alkynyl. (Exh. 1007 at col. 17).

34. Dr. Schuler considered Goulet but concluded that the reference did not disclose the RAD compound nor any RAD conjugate. (Exh. 1026 at ¶ 48).

35. Dr. Jungbluth considered Goulet but concluded that the reference did not disclose or even suggest a RAD compound or a RAD conjugate. (Exh. 1040 at ¶ 39).

IV. Principles of law

A count is a description of the interfering subject matter that sets the scope of admissible proofs on priority. Bd. R. 201. If the count covers more than one patentable invention, it may be appropriate to substitute a different count limited to a single patentable invention. *See, e.g., Goffredsen v. Banner*, 598 F.2d 589, 592, 202 USPQ 7, 10 (CCPA 1979).

As the moving party, Sedrani bears the burden of proof. Bd.R. 121(b). Therefore, Sedrani must show (1) that Count 1 covers more than one patentable invention and (2) that it is appropriate in the present circumstances to substitute the count proposed by Sedrani, i.e., proposed Count 2.

We look to each party's specification to ascertain the full scope of its claim (or portion of a claim) appearing in Count 1 and proposed Count 2. Bd.R. 200(b).

Separate patentability

A claim is anticipated only when a single prior art reference discloses each and every limitation of the claim. "An anticipatory reference, however, need not duplicate word for word what is in the claims. Anticipation can occur when a claimed limitation is 'inherent' or otherwise implicit in the relevant reference." *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). The anticipating prior art must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it. *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

The disclosure of a genus containing a limited number of compounds may anticipate a specific compound only if a person skilled in the art could at once envisage that specific compound. *In re Petering*, 301 F.2d 676, 683, 133 USPQ 275, 281 (CCPA 1962) (small genus described all compounds within the genus), *but see Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.*, 468 F.3d 1366, 81 USPQ2d 1001 (Fed. Cir. 2006) (large genus did not describe all compounds within the genus).

A disclosure of a broad genus does not necessarily render obvious each compound within its scope. *In re Baird,* 16 F.3d 380, 383, 29

USPQ2d 1550, 1552 (Fed. Cir. 1994). The question is not whether the modification could have been made, but rather "whether it was obvious to do so in light of all the relevant factors." *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997). "The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

We look to the prior art, not Molnar-Kimber's or Sedrani's specification, to determine if RAD conjugates would have been obvious in view of proposed Count 2. *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004)("in an obviousness analysis both the suggestion and the reasonable expectation of success 'must be founded in the prior art, not in the applicant's disclosure'").

V. Analysis

The Sedrani motion

Sedrani argues that substitution of proposed Count 2 for Count 1 is appropriate since Count 1 is said to cover more than one patentable invention. Sedrani contends that the RAD conjugates encompassed by

Count 1 are separately patentably from the rapamycin conjugates encompassed by Count 1. Sedrani further argues that Molnar-Kimber does not claim or disclose RAD conjugates. Sedrani contends that there is "no interference-in-fact" between it and Molnar-Kimber as to the RAD conjugates. Sedrani reasons that a count excluding the RAD conjugates of Count 1, i.e., proposed Count 2, should be substituted for Count 1.

The Sedrani evidence, primarily in the form of declaration testimony, shows that the subject matter of proposed Count 2 does not anticipate and would not have rendered obvious the RAD conjugates of Count 1.

We have before us the testimony of two credible witnesses whose testimony supports Sedrani's position that:

(1) the RAD conjugates of Count 1 are not encompassed by proposed Count 2 or the Molnar-Kimber application,

(2) neither RAD nor RAD conjugates were known in the art at the time of the invention,

(3) RAD and RAD conjugates are not obvious over rapamycin or rapamycin conjugates, and

(4) the prior art does not teach or suggest RAD or RAD conjugates.

The Sedrani witnesses contend that, given rapamycin, RAD would not have been obvious to one skilled in the art. Sedrani argues that if RAD

was not known or suggested by the prior art, then one skilled in the art could not have been motivated to form a RAD conjugate. We credit the testimony of the two Sedrani witnesses and agree with Sedrani that, since RAD has not been shown to have been known in the art, then the RAD conjugates of Count 1 were neither anticipated nor rendered obvious by the subject matter of proposed Count 2.[3]

The Molnar-Kimber opposition

Molnar-Kimber argues that the subject matter of proposed Count 2 anticipates or would have rendered obvious the RAD conjugates of Count 1.

In particular, Molnar-Kimber notes that proposed Count 2 uses the phrase "**a** rapamycin" (Paper 24 at 1) (bold in original). Molnar-Kimber, argues that the phrase "a rapamycin", which is in Molnar-Kimber claim 33 that forms part of Count 1, includes RAD. In support of its argument Molnar-Kimber directs us to its own specification. However, Molnar-Kimber has not directed us to a portion of its specification that expressly defines the phrase "a rapamycin" as including "RAD" or "rapamycin and any

[3] Sedrani also argues that "it is not possible to raise antibodies that can selectively distinguish RAD from rapamycin using the conjugates of [proposed] Count 2." (Paper 22 at 3). We do not see, and Sedrani has not adequately explained, how this argument is relevant to whether the RAD conjugates of Count 1 are the same patentable invention as the rapamycin conjugates and antibodies of proposed Count 2. For one thing, Count 1, on its face, encompasses all RAD conjugates. Sedrani has not adequately explained why we should limit the RAD conjugates of Count 1 to those that can be used to obtain monoclonal antibodies binding selectively to RAD over rapamycin.

derivative thereof" or that expressly defines the phrase in any other fashion. Molnar-Kimber has not directed us to evidence, such as testimony, indicating that one skilled in the art would understand the Molnar-Kimber disclosure to include RAD or RAD conjugates. Thus, we are unpersuaded by Molnar-Kimber's argument that the phrase "a rapamycin" as it appears in proposed Count 2 anticipates RAD.

Molnar-Kimber further argues that RAD conjugates would be obvious in view of the subject matter of proposed Count 2 especially since RAD was known in the art.

Molnar-Kimber has offered in evidence two patents in support of its position.

The first, to Cottons, is not prior art to either Molnar-Kimber's involved application or Sedrani's patent and thus cannot serve as a basis for determining what would have been obvious "at the time of the invention."

The second to Goulet provides a generic list that includes hundreds of compounds, one of which, given the proper selections, would be RAD.

Molnar-Kimber relies on reaction scheme F, which is said to show "the synthesis or a 40-O-(hydroxyalkyl)-rapamycin, where the hydroxyl-substituted alkyl group is C_1-C_8 alkyl." (Paper 24 at 2-3). The text describing reaction scheme F indicates the production of a compound

where "R^1 is unsubstituted or substituted alkyl, alkenyl, or alkynyl"[4] and without specification as to the structure of R2. (Exh. 1007 at col. 21, l. 55-col. 22, l.9). The subgenus of compounds disclosed at reaction scheme F, is considerably smaller than that generically disclosed in the Goulet patent. To arrive at RAD, given the subgenus at reaction scheme F, one skilled in the art would have to select hydroxyl substituted ethyl as R^1 and hydrogen as R^2.

The Molnar-Kimber case is devoid of credible evidence, such as testimony, indicating that one skilled in the art viewing Goulet would at once envision RAD. Molnar-Kimber has not directed us to evidence, such as testimony, that explains why one skilled in the art would have made the particular selections that would have led to RAD. On the other hand, Dr. Schuler's testimony reflects that he considered Goulet but concluded that the reference did not disclose the RAD compound or any RAD conjugate. (Exh. 1026 at ¶ 48). Dr. Jungbluth's testimony reflects that he considered Goulet but concluded that the reference did not disclose or even suggest a RAD compound or a RAD conjugate. (Exh. 1040 at ¶ 39).

[4] The illustrated reaction shows a product having a hydroxyl substituted "A" group. We understand A to be alkyl, alkenyl, or alkynyl. (Exh. 1007 at col. 17).

We credit the testimony of Dr. Schuler and Dr. Jungbluth over Molnar-Kimber's unsupported arguments that RAD is anticipated or would have been obvious in view of the Goulet patent described.

We note that Molnar-Kimber further argues that, if RAD was known, it would have been obvious to prepare RAD conjugates. In support of its contention, Molnar-Kimber points "page 12 of the Molnar-Kimber application" and the Sedrani patent. (Paper 24 at 15). However, neither Molnar-Kimber's nor Sedrani's specification is prior art for purposes of determining what would have been obvious in view of proposed Count 2.

VI. Conclusions of Law

Sedrani has sustained its burden to show that (1) the RAD conjugates of Count 1 are separately patentable from the subject matter of proposed Count 2, and (2) substitution of proposed Count 2 for Count 1 is appropriate in the circumstances of this interference.

VII. Other issues

Claim correspondence

Sedrani concedes that all of its claims correspond to proposed Count 2. and argues that the same claims that correspond to Count 1 should correspond to proposed Count 2 for both parties. (Paper 22 at 13-14). Molnar-Kimber has not argued that any of its claims that correspond to

Count 1 should not correspond to proposed Count 2. The interference will be redeclared in a separate paper to reflect the count substitution. Claim correspondence will be unchanged.

Decision

Sedrani has requested adverse judgment with respect to Count 2 after decision on its motion. (Paper 23). Judgment will be entered against Sedrani in a separate paper.

VIII. Order

Upon consideration of the record and for reasons given, it is

ORDERED that Sedrani motion 1 is GRANTED;

FURTHER ORDERED that the interference will be redeclared in a separate paper; and

FURTHER ORDERED that judgment against Sedrani will be entered in a separate paper.

/ss/ Fred E. McKelvey)
FRED E. McKELVEY)
Senior Administrative Patent Judge)
) BOARD OF
/ss/ Sally Gardner Lane) PATENT
SALLY GARDNER LANE) APPEALS
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